

Applicants: A. Wesley Prais et al.
Application No.: 10/634,567
Filing Date: August 5, 2003
Attorney Docket No.: P-5220P1 (102-523 DIV/CON/CIP II)
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REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-28 and 31-59 are in the application. Claims 11-18 presently stand withdrawn in view of a previous election.

I. Rejections Under 35 U.S.C. §112

In the Official Action, the Examiner rejected claim 12 under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner specifically stated that, “[a]mended claim 12 is unclear, the amendment recites ‘...said bevel...’ in which the only antecedent basis mentions ‘...five bevels...’.” As indicated above, claim 12 is presently withdrawn in view of the previous election. Moreover, claim 12 does not have any reference to five bevels. It is unclear to which claim the Examiner is referring. Applicants respectfully request an opportunity to respond to this rejection if it is in fact to be applied to a different claim.

The Examiner rejected claim 38 under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner asserted that there is “no support [in] Applicant’s specification or drawings for the 1-5 bevels” where “the first and third bevels each have a length greater than each of said second, fourth and fifth bevels”, as set forth in claim 38.

The Examiner's assertions are respectfully traversed.

With reference to Figs. 5, 6, 8 and 9 of Applicants' specification, the middle bevels 132a, 132b have greater lengths than the other bevels (primary bevel 130; tip bevels 134a, 134b). Based on Applicants' specification, particularly paras. [0042] – [0047], one skilled in the art would understand that the middle bevels 132a, 132b may have greater lengths than the other bevels. It is respectfully submitted that claim 38 is in accord with 35 U.S.C. §112.

II. Rejection Under 35 U.S.C. §103(a) Over Baldwin et al.

A. Baldwin et al. Fails to Disclose All of the Claim Limitations

The Examiner rejected claims 1-8, 19-25, 28-35 and 38-47 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. (U.S. Patent No. 3,071,135). The Examiner asserted that "Baldwin et al. meets the claim limitations as described above except for a needle inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel." The Examiner asserted that it would have been obvious to obtain these features.

Baldwin et al. is directed to a hollow needle. The needle includes a beveled front face 12 which includes beveled side faces 13. A heel surface 15 is also provided. (Col. 3, ll. 12-16). The heel surface 15 is "dished" to define a depression or recess 17, as clearly shown in Fig. 3.

(Col. 3, ll. 41-50). For the reasons set forth below, it is respectfully submitted that, however, Baldwin et al. fails to disclose or suggest all of the claim limitations of the rejected claims.

1. Claim 1

Claim 1 is directed to a syringe assembly which includes a needle cannula “having a multi-beveled point including a plurality of planar bevels extending at different angles relative to said central axis, including a primary bevel, a pair of tip bevels and a pair of middle bevels”. In contrast, Baldwin et al. does not provide at least five planar bevels in its device. As clearly shown in Fig. 3, the recess 17 is dished and not formed planar. Also, the shape of the heel 15 about the recess 17 is unclear, as well as, of the shape of the beveled side faces 13. In any regard, at least five planar surfaces are not shown or disclosed in Baldwin et al. Moreover, there is no suggestion or motivation to modify Baldwin et al., since the recess 17 must be dished. (See, col. 3, ll. 41-50).

In the Official Action, the Examiner asserted that “Baldwin et al. discloses a series of planar bevels (13, 19, 12, 15, 17) (Figures 1 and 3)” and that “Applicant has not claimed that the bevels are on the same plane or on a single plane”. Contrary to the Examiner’s assertion, and as set forth above, the bevel 17 is dished and not formed planar. As shown in Figs. 5, 6, 8 and 9 of Applicants’ specification, all the bevels are generally flat, i.e., planar. Baldwin et al. does not disclose or suggest the use of five planar bevels, as set forth in claim 1. It is respectfully submitted that claim 1, along with dependent claims 2-8, are patentable over Baldwin et al.

2. Claim 19

Claim 19 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point “comprised of a primary bevel, a pair of tip bevels, and a pair of middle bevels” wherein “said planar angles of said primary bevel and said pair of middle bevels are substantially equal.” There is no disclosure or suggestion in Baldwin et al. of what angles are to be used in forming the side faces 13, the heel 15, or the recess 17. As such, there is no disclosure or suggestion of having a planar angle for at least three different bevels be substantially equal (i.e., the planar angle of a primary bevel plus the planar angle of a pair of middle bevels).

In the Official Action, the Examiner asserted that “the rotational and planar angles of Baldwin et al.’s bevels are *substantially equal*”. There is absolutely no disclosure or suggestion in Baldwin et al. of having the planar angle of bevels at two different locations be substantially equal. The only possible disclosure for such is arguably in Baldwin et al.’s figures. However, as set forth in MPEP §2125, proportions of features in a drawing can not be relied on where there is no indication that drawings are to scale. (See, MPEP §2125 (“When the reference does not disclose that the drawings are to scale and as silent as to dimensions, arguments based on measurement of the drawing features are of little value.”)). The planar angles of the bevels in Baldwin et al. require proportionate estimates to be evaluated. Proportions, however, cannot be relied upon. It is respectfully submitted that claim 19, along with dependent claims 20-25, are patentable over Baldwin et al.

3. Claim 28

Claim 28 is directed to a syringe assembly which includes a needle cannula having a multi-beveled point “comprised of five bevels, wherein each of said five bevels is provided on said cannula at a planar angle defined between said central axis and a reference plane” and “wherein each of said five bevels is provided on said cannula at an angle of rotation about said central axis”. Further, “a first planar angle is defined at said bevel corresponding to a first rotational angle, a second planar angle is defined at said bevel corresponding to a second rotational angle, said first and second rotational angles being different with said first and second planar angles being substantially equal.” Baldwin et al. does not provide such an arrangement. Both portions of the heel 15 are located at the same rotational angle relative to a central axis, while both side faces 13 are also located at the same rotational angle relative to the central axis. As discussed above, there is no disclosure in Baldwin et al. of planar angles. Even taking that both of the side faces 13 may be formed at the same planar angle or that both of the heel portions 15 about the recess 17 may be formed at the same planar angle, both side faces 13 and both heel portions 15 are at the same, not different, rotational angle relative to each other; there is no disclosure or suggestion in Baldwin et al. to have bevels at two different rotational-angle locations with the same planar angle. In other words, there is no disclosure or suggestion to have two or more of a side face 13, a heel portion 15, and/or recess 17 at the same planar angle. It is respectfully submitted that claim 28, along with dependent claims 29-35, are patentable over Baldwin et al.

4. Claim 38

Claim 38 is directed to a syringe assembly which includes a needle cannula having “first, second, third, fourth and fifth bevels bounding” an opening defined through a first end of the needle cannula. The bevels are arranged in a specific contiguous sequence “wherein said first and third bevels each have a greater length than each of said second bevel, said fourth bevel, and said fifth bevel.” Baldwin et al. fails to disclose such an arrangement. With the specific claimed contiguous sequence, two bevels must be separated by a bevel of shorter length with those separated bevels being also greater in length than two other formed bevels. With respect to Baldwin et al., it can be argued that portions of the heel 15 about the recess 17 have greater length than the recess 17. However, the side faces 13 clearly have greater length than the heel portions 15. Claim 38 would require Baldwin et al. to have heel portions 15 with greater length than the side faces 13. It is respectfully submitted that claim 38, along with dependent claims 39-47, are patentable over Baldwin et al.

B. Claimed Features Are Non-Obvious

In the Official Action, the Examiner asserted that the claimed needle ranges are “obvious since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice...and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.” The Examiner’s assertions are respectfully traversed.

The claimed ranges, including angles and cannula thicknesses, are critical limitations which provide meaningful and beneficial results. These limitations are not the result of optimization or routine experimentation. In the context of the invention as claimed, including the specific bevel arrangement, it has been found that the subject invention provides reduced needle penetration forces as compared to existing products. Paragraph [0049] and the following table in Applicants' specification sets forth the obtainable improvement based on the inventive arrangement. It is respectfully submitted that the claimed ranges are critical and non-obvious in obtaining these tangible improvements. This criticality further supports the patentability of claims 1-8, 19-25, 28, 31-35 and 38-47 over Baldwin et al.

III. Rejection Under 35 U.S.C. §103(a) Over De Luca

The Examiner rejected claims 50-57 under 35 U.S.C. §103(a) as being allegedly unpatentable over De Luca (U.S. Patent No. 3,308,822).

De Luca is directed to a hypodermic needle which includes multiple facets. As shown in Fig. 10, open end of the lumen 14 is bound by a front face 12 and two planar faces 13 and 16. As such, there are three bevels bounding the open end 14. The front face 12 is located furthest from the pointed tip of the device.

Claim 50 is directed to a syringe assembly which includes a needle cannula having a plurality of discrete bevels "wherein one of said plurality of discrete bevels is located furthest

from said point and has a length shorter than any of said other ones of said plurality of discrete bevels.” In contrast, De Luca provides a bevel having the greatest length, not the shortest length, at a location furthest from the tip of the device. There is no disclosure or suggestion in De Luca to provide otherwise.

In the Official Action, the Examiner asserted that “the De Luca reference discloses a bevel (12) located furthest from a point having a length shorter than any of said other ones (16) as shown in Figure 8.” It is unclear how the bevel 12 is shorter than the bevel 16 in De Luca. With reference to Fig. 10, the bevel 16 is shown to be almost equivalent in length to the bevel 12. However, as shown in Fig. 8, the bevel 12 is arched-shaped and has a length twice of that shown in Fig. 10. The bevel 12 clearly has a length longer than the bevel 16. It is respectfully submitted that claim 50, along with dependent claims 51-57, are patentable over De Luca.

IV. Rejection Under 35 U.S.C. §103(a) Over Baldwin et al. Or De Luca In View of Hausser

The Examiner rejected claims 9-10, 26-27, 36-37, 48-49 and 58-59 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. or De Luca in view of Hausser (U.S. Patent No. 5,385,555). The Examiner asserted that Baldwin et al. or De Luca meet the claimed limitations “except for a needle shield with a specific Shore hardness’s [sic] as claimed.” The Examiner cited needle shield 36 of Hausser as allegedly overcoming this deficiency.

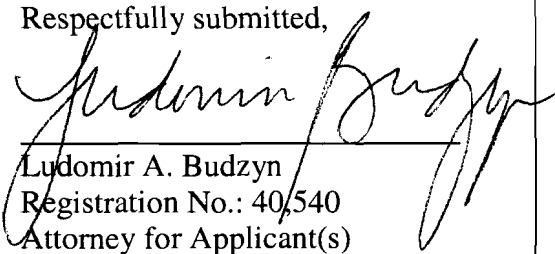
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As set forth at col. 5, ll. 40-43, the safety shield in Hausser is disclosed as being formed generically from a "thermoplastic material". The rejected claims of the subject application are directed to a specific material, particularly a styrene block thermoplastic elastomer, which is absolutely not disclosed or suggested in Hausser. The advantages of this specific material are discussed extensively in Applicants' specification, such as at paras. [0033] - [0041]. Preservation of needle sharpness and improved sterilization are some of the obtained benefits of the claimed material and this material is not at all obvious from Hausser. It is respectfully submitted that claims 9-10, 26-27, 36-37, 48-49 and 58-59 each provide additional bases of patentability beyond that discussed above and are each, in turn, patentable over Baldwin et al., De Luca and Hausser, each taken alone or in combination.

V. Conclusion

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,


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